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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,144	09/26/2003	Lawrence Tamarkin	CYT-0027	8073
95280 7590 11/05/2010 Johnson & Associates 317A E. Liberty Street			EXAMINER	
			ANGELL, JON E	
Savannah, GA	31401		ART UNIT	PAPER NUMBER
			1635	
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			11/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/672 144 TAMARKIN ET AL. Office Action Summary Examiner Art Unit J. E. ANGELL 1635 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 October 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 27-31 and 35-48 is/are pending in the application. 4a) Of the above claim(s) 47 and 48 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 37-42,45 and 46 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/06)

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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## DETAILED ACTION

This Action is in response to the communication filed on 10/14/2010.

The amendment filed 10/14/2010 is acknowledged and has been entered.

Claims 27-31, 35-48 are currently pending in the application and are addressed herein.

Applicant's argument submitted 10/14/2010 that claims 37-42 and 45-48 are directed to targeting molecules for which no species election requirement was made has been considered and, with respect to claims 37-42, 45-46, is persuasive. However, it is respectfully pointed out that claims 47 and 47 are drawn to the method of claim 4 wherein the biologically active molecule is not TNF-alpha or IL-12, which are the elected biologically active factors as previously set forth. Therefore, claims 47 and 48 (as well as previously examined claims remain withdrawn from consideration and claims 37-42, 45-46 are further considered herein. However, upon further consideration of claims 37-42 and 45-46, it has been determined that claims 37-42 and 45-46 encompass different species which necessitates the election of single targeting molecule of claims 37-42 and 45-46 before prosecution can proceed. It is noted that claims 27-31, 35 and 6 will be addressed, as well as Applicants response submitted 10/14/2010, will be addressed in the action following the election of species as set forth herein.

## Election/Restrictions

 This application contains claims directed to the following patentably distinct species of targeting molecules as encompassed by previously withdrawn claims 37-42, 45-46:

The species of targeting molecules are: cancer cell specific antigen, polyclonal antibody, monoclonal antibody.

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Furthermore, should Applicant elect the species "cancer cell specific antigen" further election of one of the following claimed species of cancer cell specific antigens is also required: MART. MAGE. BAGE.

2. The species are independent or distinct because each species is structurally and functionally distinct from the other species and a search of one species would not necessarily fully cover the search required for the other claimed species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 37-42, 45, 46 are considered generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: Each species is structurally distinct from the other species, thus each requires a different search, and a search of one species would not necessarily fully cover the search required for the other claimed species.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include

(i) an election of a species or a grouping of patentably indistinct species to be examined
even though the requirement <u>may</u> be traversed (37 CFR 1.143) and (ii) identification of the
claims encompassing the elected species or grouping of patentably indistinct species,
including any claims subsequently added. An argument that a claim is allowable or that all
claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out Application/Control Number: 10/672,144

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supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. ANGELL whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. ANGELL/ Primary Examiner, Art Unit 1635